

## REMARKS

The presently-claimed invention relates to novel mammalian REMODEL polypeptides.

Claims 4, 5, 21 and 37-44 are pending in the current application. By way of the present Amendment, Applicants have amended claims 21, 37, and 43, and have canceled claims 4, 5, 39, 41 and 42. No new matter has been added by way of these amendments.

### Objections to Specification

The Examiner has objected to the specification for containing an “embedded hyperlink.” Applicants have corrected all four instances of embedded hyperlinks. Applicants have merely made clerical corrections by correcting the format of the internet address, and therefore, no new matter has been added by way of these amendments.

The Examiner has also noted that the specification should be amended to reflect the status of the priority application. Therefore, by way of the present Amendment, Applicants have amended the specification to recite the correct priority information. No new matter was added by way of this amendment, as Applicants set forth the correct priority information in the application transmittal sheet, the preliminary amendment, and in the information disclosure statement filed at the initial time of filing of the present application.

### Claim Election

Applicants acknowledge the Examiner’s withdrawal of claims 38 and 40 from consideration as being drawn to the non-elected invention.

Applicants respectfully disagree with the Examiner’s attempt to withdraw claim 44 from consideration. Claim 44 is directed to a recombinant cell comprising the isolated polypeptide of claim 37, and the Examiner has indicated that claim 37 is indeed within the field of the elected invention. Because a search of claim 44 would not require any substantial effort beyond that required for the search of claim 37, Applicants respectfully submit that claim 44 is indeed part of the group of elected claims, and request that the Examiner kindly reconsider and retract the withdrawal of claim 44, and examine claim 44 on the merits.

In compliance with the claim election, and in order to place the claims within the scope of the elected invention, Applicants have amended claims 21, 37, and 42, and have canceled claims 4, 5, 39, and 41.

#### Claim Objections

Applicants gratefully note that the Examiner has indicated that claim 37 would otherwise be allowable, but has objected to claim 37 for the recitation of non-elected embodiments, and further, that claims 39 and 43 would otherwise be allowable, but has objected to claims 39 and 43 for the dependence of the claims on an objected base claim and a rejected base claim, respectively.

Applicants have therefore amended claim 37 to remove recitation to the non-elected embodiments. Therefore, it is Applicants' understanding that claim 37 should now be in full condition for allowance. Applicants have cancelled claim 39, as claims 37 and 39 were identical in scope after the amendment of claim 37 herein. Applicants further respectfully submit that claim 44, which depends from claim 37, is therefore in full condition for allowance and request examination of claim 44 on the merits and notification of the allowance of claim 44 in due course.

Applicants have amended claim 42, from which claim 43 depends, such that claim 42 does not recite any non-elected embodiments. Accordingly, applicants respectfully submit that objected claim 43 is also in full condition for allowance, and request notification of the allowance of claim 43 in due course.

#### Rejection of Claims 4, 5, 21 and 41 under 35 U.S.C. §112, first paragraph - enablement

Claims 4, 5, 21 and 41 were rejected under 35 U.S.C. §112, first paragraph, because in the Examiner's opinion, the claims are not enabled. In the Examiner's view, the claims are not enabled in that the specification does not support any isolated polypeptide comprising any mammalian REMODEL, wherein the REMODEL molecule shares at least about 6% sequence identity with SEQ ID NO:4. The Examiner's rejection appears to be based on the level of percent sequence identity recited in the claims.

Applicants have cancelled claims 4, 5 and 41, rendering the Examiner's rejection of these claims moot. Claim 21 has been amended to depend from amended claim 37, which

encompasses a polypeptide comprising a REMODEL polypeptide as set forth in SEQ ID NO:4. Applicants respectfully submit that the invention as set forth in amended claim 21 is enabled by the specification as filed under the current law pursuant to 35 U.S.C. § 112, first paragraph, for the following reasons.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. MPEP §2164.01 (citing *In re Angstadt*, 537 F.2d 498, 504 (C.C.P.A. 1976)). The fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. *Id.* Further, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. MPEP §2164.05(a) (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991)). Therefore, under current law, enablement does not require numerous working examples and experimentation is allowed so long as it is not undue.

Applicants respectfully submit that the present invention is more than adequately enabled for SEQ ID NO:4, because the instant application provides the skilled artisan with abundant guidance in the characteristics of that sequence. Applicants respectfully submit that the instant application teaches how to identify, isolate, obtain, purify, produce, characterize and assay a REMODEL polypeptide as set forth in SEQ ID NO:4. Support can be found throughout the specification, and in particular, in the Experimental Examples.

In sum, claim 21 is enabled by the disclosure provided in the specification as filed as required under 35 U.S.C. §112, first paragraph. Therefore, Applicants respectfully request that the rejection of this claim be reconsidered and withdrawn.

Rejection of claims 4, 5, 21 and 41 under 35 U.S.C. § 112, first paragraph – written description

The Examiner rejected claims 4, 5, 21 and 41 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such as way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed (a “written description” rejection). The Examiner apparently rejects the claim language drawn to isolated polypeptides comprising mammalian REMODEL, wherein the REMODEL molecule shares at least about 6% sequence

identity with SEQ ID NO:4. The Examiner's rejection appears to be based on the level of percent sequence identity recited in the claims.

Applicants have cancelled claims 4, 5 and 41, rendering the Examiner's rejection of these claims moot. Applicants respectfully submit that the claimed invention, as set forth in amended claim 21, is supported by more than adequate written description in the specification as filed under the current law pursuant to 35 U.S.C. § 112, first paragraph, for the following reasons.

It appears to be the Examiner's view that the disclosure only provides a limited number of species that satisfy the written description requirement. While not necessarily agreeing with the Examiner's reasoning, Applicants have amended claim 21 herein to remove language directed to non-elected inventions. Claim 21 now recites a pharmaceutical composition comprising a REMODEL polypeptide as set forth in SEQ ID NO:4. The instant specification sets forth SEQ ID NO:4, as well as how to identify, isolate, obtain, purify, produce, characterize and assay a REMODEL polypeptide as set forth in SEQ ID NO:4. Because the amendment to claim 21 is fully supported in the specification as filed, the amendment therefore adds no new matter.

Therefore, Applicants submit that amended claim 21 satisfies the written description requirement. Accordingly, Applicants respectfully submit that the Examiner's written description rejection has either been overcome or no longer applies, and request reconsideration and withdrawal of the rejection.

#### Rejections Under 35 U.S.C. §§ 102(a) and 102(e)(1)

Claims 4, 5, 21, 41 and 42 were rejected under 35 U.S.C. §§ 102(a) and 102(e)(1) as being anticipated by WO 00/52151 (Tang, et al.). Applicants have cancelled claims 4, 5, 41 and 42, rendering the Examiner's rejection of these claims moot. Applicants respectfully submit that claim 21, as presently amended, is not anticipated by Tang et al. for the following reasons.

35 U.S.C. § 102(a) provides that:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent[.]

35 U.S.C. § 102(e)(1) provides that:

A person shall be entitled to a patent unless –  
(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent[.]

It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, Tang et al. must describe each and every element of claim 21 in order to anticipate the claim under either 35 U.S.C. § 102(a) or 35 U.S.C. § 102(e)(1).

Applicants respectfully submit that Tang et al. does not teach each and every element of claim 21. Applicants claims relate to a REMODEL as set forth in SEQ ID NO:4, which is a 243 amino acid polypeptide. Specifically, claim 21 relates to a REMODEL consisting of SEQ ID NO:24. Alternatively, Tang et al. does not offer any guidance or provide any disclosure as to the specific 243 amino acid sequence of SEQ ID NO:4 of the instant invention, nor does Tang teach or suggest how or why the skilled artisan would identify any specific 243 amino acid portion within the sequence set forth in Tang et al.

Because Tang et al. does not disclose or teach SEQ ID NO:4 of the present invention, Tang et al. cannot constitute prior art with regard to claim 21, since Tang et al. is not an "enabling disclosure." See, e.g., MPEP §2121.01 (citing *In re Hoeksema*, 158 USPQ 596 (CCPA 1968)). Thus, Applicants respectfully submit that Tang et al. does contain an "enabling disclosure" and therefore cannot be considered prior art for purposes of anticipating Applicants' invention. *Id.* (citing *In re Donohue*, 226 USPQ 619 (Fed. Cir. 1985)).

Further, the mere disclosure in Tang et al. of larger polypeptide than Applicants' claimed invention is, at most, an invitation to experiment and cannot anticipate claim 21. This is because in order for a reference to be prior art, the reference must be enabling, and there is absolutely no guidance in Tang et al. as to what the identity of any particular polypeptide fragments might be. Therefore, Tang et al. cannot anticipate claim 21 under 35 U.S.C. §§ 102(a) and 102(e)(1), and Applicants respectfully request reconsideration and withdrawal of the rejections.

Summary

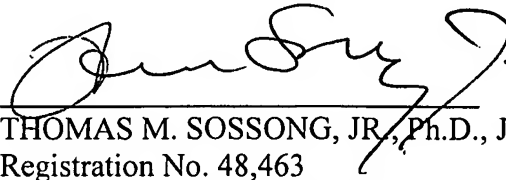
Applicants respectfully submit that the pending claims are fully supported in the specification as filed, and that no new matter has been added by way of the present Amendment.

Favorable examination and allowance of the claims is hereby requested.

Respectfully submitted,

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